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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,218	11/30/2001	Lonnie O'Neal Ingram	BCI-009C3C4CN	1895

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001218

Applicant(s)

Ingram et al.

Examiner

T. Saldha

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/30/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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DETAILED ACTION

1. Applicants' filing of this continuation application, dated 11.30.01, is acknowledged. Claims 1-18 are pending.

2. *Enablement*

Claims 1-3, 5-12 & 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant strain of *Bacillus subtilis* YB886 (pLOI1500) transformed with alcohol dehydrogenase (ADHII) and pyruvate decarboxylase (PDC) genes from *Zymomonas mobilis*, does not reasonably provide enablement for any eukaryotic cell or a method for ethanol production, including any animal cell, insect cell, or fungal cell transformed with genes encoding alcohol dehydrogenase (ADHII) and pyruvate decarboxylase (PDC), or polysaccharase(s) gene(s) to produce sufficient levels of ethanol as a fermentation product (claims 1-3, 5-12 & 17) and further develop a method of transforming any eukaryotic cell with a gene encoding any enzyme which would degrade oligosaccharides (claims 14-16).

The specification provides the example of recombinant strain of *Bacillus subtilis* YB886 (pLOI1500) transformed with ADHII and PDC activities. The specification describes 1 species and 2 strains of *Bacillus* (page 22, lines 2-5) after testing several species and strains as alternate hosts, which is an indication that not all species or strains within the same genera can so easily be transformed with the disclosed genes. Given the unpredictability shown above, extrapolating the guidance provided in the instant specification to be able to (a) express the alcohol dehydrogenase and pyruvate decarboxylase or polysaccharase(s) gene(s) obtained from any source in a eukaryotic

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cell expression system and sufficient levels would require guidance to (b) obtaining the genes from any source, © optimizing the compatibility of such an expression system, i.e., whether a eukaryotic cell, such as from an insect, fungi or animal permit such a transformation of the genes for sufficient ethanol production, from excess of the product may prove toxic or detrimental to the cell system in question, which may be due to the lack of tolerance to higher levels of ethanol. Other bacteria, for example, *E. coli*, when transformed with genes coding for pyruvate decarboxylase and aldehyde dehydrogenase does not tolerate greater than 7.5% ethanol, as is well known in the art. (d) Guidance is also lacking in the transformation of the fermentative genes [alcohol dehydrogenase (ADHII) and pyruvate decarboxylase (PDC) or polysaccharase(s) gene(s)] into non-fermentative cell types, such as insect or animals or fungi, lack of which may result in non-viable constructs from producing ethanol any levels. (e) Adequate guidance to sustaining growth conditions or culture medium required for such a diverse group of cultures such as that claimed are also lacking, and no such conditions are described that would adequately support the transformants of varying eukaryotic cell types given the conditions for *Bacillus* species. (f) It is also well known that diverse metabolic enzymes are operative in different cell types and governing unique functions. How, then transforming a eukaryotic cell with that of enzymes of fermentation would fit into metabolic scheme of the cell. No examples are provided of successfully manipulating various eukaryotic cell types in order to successfully reorganize the genes into the specific pathways of the individual eukaryotic cell, or reduce the accumulation of acidic metabolite, without such a guidance, the experiment left to those skilled in the art will be undue.

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3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-18 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of prior U.S. Patent No. 5,916,787.

Claims 1-18 in U.S. Patent No. 5,916,787 are identical to that claimed in the instant application and therefore anticipates the claims.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application.
See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(a) Claims 1-8 are rejected under the judicially created doctrine of double patenting over claims 1-2 of U. S. Patent No. **5,482,846**, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Claims 1-2 of U.S. Patent No. **5,482,846** are drawn to a species of selected gram-positive bacteria transformed with the alcohol dehydrogenase & pyruvate decarboxylase genes and method of use, as compared to any gram-positive bacteria and method of use, the genus claimed in the instant application. Since a species anticipates the genus [& genus obviates a species], the patented species claims of U.S. Patent No. **5,482,846** anticipates the instantly claimed generic claims.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Tekchand Saidha
Primary Examiner, Art Unit 1652
July 25, 2003